

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

ANNETTE S. RUIZ,

Plaintiff,

v.

MEDTRONIC, INC. et al.,

Defendants.

No. 2:24-cv-00489-TLN-SCR

ORDER

This matter is before the Court on Defendants Medtronic, Inc. and Covidien, LP's (collectively, "Defendants") Motion to Dismiss Plaintiff's Second Amended Complaint ("SAC"). (ECF No. 23.) Plaintiff filed an opposition, and Defendants filed a reply. (ECF Nos. 32, 34.) For the following reasons, the Court DENIES Defendants' Motion.

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I. FACTUAL AND PROCEDURAL BACKGROUND

The instant action arises out of a products liability dispute involving an allegedly defective surgical tool. Following this Court’s prior order dismissing the First Amended Complaint, (ECF No. 21), Plaintiff filed a SAC on February 19, 2025 (ECF No. 22). Plaintiff alleges during her hysterectomy procedure at Kaiser Hospital, her health care providers used a tool called the Endoclinch Grasper (hereinafter “Grasper tool”) which was designed, manufactured, marketed and sold by Defendants. (*Id.* ¶¶ 13–14.) During the surgery, a screw or pin from the Grasper tool separated from the tool and lodged itself in Plaintiff’s body. (*Id.* ¶ 15.) Following the surgery, Plaintiff experienced pain and loss of quality of life. (*Id.* ¶ 16.)

In November 2021, an x-ray revealed there was an object in Plaintiff’s pelvis “from an unknown source.” (*Id.* ¶ 17.) In January 2022, Plaintiff was advised of this finding and scheduled for a second surgery. (*Id.* ¶ 18.) At this time, Plaintiff’s surgeon advised her that the retained object was from Defendants’ Grasper tool that was used during Plaintiff’s surgery. (*Id.*)

On March 10, 2022, Plaintiff had a second surgery to remove the screw or pin from inside her body. (*Id.* ¶ 19.) After the object was removed, Plaintiff’s surgeon told Plaintiff the object was a screw or pin from the Grasper tool. (*Id.*) Plaintiff was given an “exemplar Endoclinch Grasper” and told that an adverse event/MAUDE defect report was filed about the event. (*Id.*) Further, Plaintiff was told Kaiser stopped using the Grasper tool. (*Id.*)

Based on these allegations, Plaintiff alleged the following claims: (1) strict liability; (2) negligence; and (3) breach of express warranty. (*See generally id.*) Defendants now move to dismiss Plaintiff’s SAC in its entirety. (ECF No. 23.)

II. STANDARD OF LAW

A motion to dismiss for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure (“Rule”) 12(b)(6) tests the legal sufficiency of a complaint. *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). Rule 8(a) requires that a pleading contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009). The factual allegations of the complaint must be accepted as true. *Cruz v. Beto*, 405 U.S. 319, 322 (1972). Additionally,

1 the court must give the plaintiff the benefit of every reasonable inference to be drawn from the
2 “well-pleaded” allegations of the complaint. *Retail Clerks Int’l Ass’n v. Schermerhorn*, 373 U.S.
3 746, 753 n.6 (1963). A plaintiff need not allege “‘specific facts’ beyond those necessary to state
4 his claim and the grounds showing entitlement to relief.” *Bell Atl. Corp. v. Twombly*, 550 U.S.
5 544, 570 (2007) (internal citation omitted).

6 Nevertheless, a court “need not assume the truth of legal conclusions cast in the form of
7 factual allegations.” *U.S. ex rel. Chunie v. Ringrose*, 788 F.2d 638, 643 n.2 (9th Cir. 1986).
8 While Rule 8(a) does not require detailed factual allegations, “it demands more than an
9 unadorned, the defendant-unlawfully-harmed-me accusation.” *Iqbal*, 556 U.S. at 678. A
10 pleading is insufficient if it offers mere “labels and conclusions” or “a formulaic recitation of the
11 elements of a cause of action.” *Twombly*, 550 U.S. at 555; *see also Iqbal*, 556 U.S. at 678
12 (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory
13 statements, do not suffice.”). Thus, “[c]onclusory allegations of law and unwarranted inferences
14 are insufficient to defeat a motion to dismiss” for failure to state a claim. *Adams v. Johnson*, 355
15 F.3d 1179, 1183 (9th Cir. 2004) (citations omitted). Moreover, it is inappropriate to assume the
16 plaintiff “can prove facts that it has not alleged or that the defendants have violated the . . . laws
17 in ways that have not been alleged.” *Associated Gen. Contractors of Cal., Inc. v. Cal. State*
18 *Council of Carpenters*, 459 U.S. 519, 526 (1983).

19 Ultimately, a court may not dismiss a complaint in which the plaintiff has alleged “enough
20 facts to state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. “A claim
21 has facial plausibility when the plaintiff pleads factual content that allows the court to draw the
22 reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at
23 680. While the plausibility requirement is not akin to a probability requirement, it demands more
24 than “a sheer possibility that a defendant has acted unlawfully.” *Id.* at 678. This plausibility
25 inquiry is “a context-specific task that requires the reviewing court to draw on its judicial
26 experience and common sense.” *Id.* at 679. Thus, only where a plaintiff fails to “nudge [his or
27 her] claims . . . across the line from conceivable to plausible[,]” is the complaint properly
28 dismissed. *Id.* at 680 (internal quotations omitted).

III. ANALYSIS

Defendants argue Plaintiff fails to comply with the Federal Rules of Civil Procedure and fails to allege sufficient plausible facts to support any of her claims — strict liability, negligence, or breach of express warranty. (ECF No. 23 at 9–19.) Plaintiff disagrees and argues Defendants attempt to impose a higher factual standard of pleading than is required in a motion to dismiss. (ECF No. 32 at 5.) The Court addresses each claim in turn.

A. Strict Liability

A manufacturer is strictly liable for injuries caused by three different types of defects: (1) a manufacturing defect, (2) a design defect, and (3) a warning defect. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 995 (1991). Defendants argue Plaintiff’s strict liability claim should be dismissed because Plaintiff has not proven they are liable under any theory. (ECF No. 23 at 12.) The Court evaluates Plaintiff’s claim under each theory below.

i. *Manufacturing Defect*

To adequately plead a manufacturing defect under California law, Plaintiff must establish the Grasper tool “differs from the manufacturer’s intended result or from other ostensibly identical units of the same product line[.]” *Barker v. Lull Eng’g Co.*, 20 Cal. 3d 413, 429 (1978), and the alleged defect caused the plaintiff’s injury, *Soule v. Gen. Motors Corp.*, 8 Cal. 4th 548, 572 (1994). Therefore, to survive a motion to dismiss under Rule 12(b)(6), a plaintiff “must identify/explain how the [product] either deviated from [the manufacturer’s] intended result/design or how the [product] deviated from other seemingly identical [products].” *Garcia v. Sanofi Pasteur Inc.*, 617 F. Supp. 3d 1169, 1172 (E.D. Cal. 2022) (citation omitted).

Defendants argue Plaintiff’s bare allegations that the Grasper tool had a manufacturing defect are insufficient and fail to establish how the Grasper tool deviated from its intended design.¹ (ECF No. 23 at 14.) Defendants argue Plaintiff’s new allegations are not “concrete

¹ Defendants cite to several cases to purportedly show how federal courts in the Ninth Circuit have repeatedly dismissed factually deficient manufacturing defect claims that did not sufficiently allege how the product at issue deviated from its intended design. (EF No. 23 at 13–14.) However, Defendants fail to provide any meaningful analysis or explain how these cases are analogous to the instant action. As such, the Court does not address this particularly long string cite.

1 facts” but speculation. (*Id.*) Defendants additionally argue Plaintiff provides no affidavit to back
2 up the surgeon’s assertion that the screw or pin dropped from the Grasper tool. (*Id.* at 14–15.)

3 In opposition, Plaintiff argues she has plausibly stated a manufacturing defect theory and
4 copies allegations from the SAC into a table that spans approximately five pages. (ECF No. 32 at
5 7–11.) In reply, Defendants once again argue Plaintiff fails to allege how the Grasper tool
6 deviated from its intended design and therefore Plaintiff’s SAC must be dismissed. (ECF No. 34
7 at 7–9 (citing *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010).))

8 The Court finds Defendants position unavailing. At the motion to dismiss stage, the Court
9 does not require Plaintiff to support her allegations with affidavits. Instead, Plaintiff is required
10 to allege “a short and plain statement” showing she is entitled to relief. Fed. R. Civ. P. 8.
11 Plaintiff is also not required to prove her claim at this stage as Defendants appear to suggest, nor
12 could she without discovery.

13 In the Court’s prior order, Plaintiff’s strict liability claim based on a manufacturing defect
14 theory was dismissed because Plaintiff provided only bare legal conclusions that the Grasper tool
15 deviated from the manufacturer’s intended design. (ECF No. 21 at 6.) Here, the Court finds
16 Plaintiff has cured this defect. Specifically, Plaintiff alleges the screw or pin on the Grasper tool
17 was not properly attached, was the wrong size, was made from the wrong materials, and was not
18 checked to ensure it was securely fastened as required pursuant to manufacturer specifications.
19 (ECF No. 22 ¶ 22.) While Defendants argue these allegations are pure speculation, when drawing
20 all reasonable inferences in Plaintiff’s favor, the Court finds these allegations plausibly identify
21 and explain how the Grasper tool used during Plaintiff’s surgery deviated from its intended
22 design.

23 In sum, Plaintiff has sufficiently pleaded the existence of a manufacturing defect. The
24 Court DENIES Defendants’ Motion to Dismiss Plaintiff’s strict liability claim based on a
25 manufacturing defect theory.

26 *ii. Design Defect*

27 Under the “consumer expectations test,” which the Court again presumes Plaintiff is
28 utilizing here, a product’s design is defective if the product fails to “perform as safely as an

1 ordinary consumer would expect when used in an intended or reasonably foreseeable manner[.]”
2 *Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 180 (2016) (internal citations omitted).

3 Defendants argue Plaintiff’s SAC “only offers empty conjecture.” (ECF No. 23 at 16.)
4 Specifically, Defendants argue Plaintiff’s allegation that the Grasper tool did not include adequate
5 safeguards like a locking mechanism fails because the Grasper tool was already equipped with an
6 on/off ratchet switch that acted like a locking mechanism. (*Id.*) According to Defendants, it is
7 infeasible to add another locking mechanism to the Grasper tool. (*Id.*)

8 In opposition, Plaintiff argues they have sufficiently alleged a design defect claim based
9 on currently available information. (ECF No. 32 at 17.) Specifically, Plaintiff argues the SAC
10 sufficiently alleges an ordinary consumer would not expect parts on a surgical tool to fall off
11 during surgery. (*Id.*) In reply, Defendants contend Plaintiff fails to allege a series of facts,
12 including whether the surgeon during the initial surgery noticed the Grasper tool fail. (ECF No.
13 34 at 9.)

14 The Court previously dismissed Plaintiff’s strict liability claim based on a design defect
15 theory because Plaintiff did not explain how the Grasper tool failed the ordinary consumer’s
16 safety expectations nor explained how the product design caused Plaintiff harm. (ECF No. 21 at
17 7 (citing *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010).) In the SAC,
18 Plaintiff has added allegations to sufficiently rectify this. Specifically, Plaintiff alleges both that
19 the Grasper tool did not meet the consumer’s expectation for safety because a pin or screw fell
20 from the Grasper tool during surgery and the product design caused Plaintiff harm by failing to
21 contain adequate safeguards (such as a locking mechanism) to prevent such failures. (ECF No. 4
22 ¶¶ 31–34.) While Defendants argue it was infeasible to add another locking mechanism, (ECF
23 No. 23 at 16), now is not the time to contest the merits of Plaintiff’s claim. At this stage, the
24 Court accepts Plaintiff’s factual allegations as true. *Cruz*, 405 U.S. at 322. In so doing, the Court
25 finds Plaintiff has sufficiently alleged a strict liability claim under a design defect theory.
26 Therefore, the Court DENIES Defendants’ Motion to Dismiss Plaintiff’s strict liability claim
27 based on a design defect theory.

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1 iii. *Failure to Warn*

2 Under California law, a manufacturer is liable for strict liability under a failure to warn
3 theory if Defendants “did not adequately warn of a particular risk that was known or knowable in
4 light of the generally recognized and prevailing best scientific and medical knowledge available
5 at the time of manufacture and distribution.” *Carlin v. Superior Ct.*, 13 Cal. 4th 1104, 1112
6 (1996). California also applies the “learned intermediary” doctrine, which provides that the duty
7 to warn in the case of medical devices runs to the physician — not the patient. *See Zetz v. Bos.*
8 *Sci. Corp.*, 398 F. Supp. 3d 700, 706 (E.D. Cal. 2019) (citing *Carlin*, 13 Cal. 4th at 1116).

9 Defendants argue Plaintiff fails to adequately allege causation, “lacks any
10 contemporaneous documentation from the [i]nitial [s]urgery” and does not provide which
11 warnings or materials Plaintiff’s surgeon reviewed. (ECF No. 23 at 17.) In opposition, Plaintiff
12 contends there are now sufficient allegations to state a claim for strict liability under a failure to
13 warn theory. (ECF No. 32 at 18.) In reply, Defendants maintain Plaintiff fails to sufficiently
14 allege a strict liability failure to warn claim arguing Plaintiff’s allegations are speculative and
15 Plaintiff does not allege facts to show the screw or pin came from the Grasper tool. (ECF No. 34
16 at 9–10.)

17 The Court finds Defendants arguments unavailing. First, Plaintiff sufficiently alleges the
18 screw or pin came from the Grasper tool. (*See, e.g.*, ECF No. 22 ¶ 31 (“The . . . pin/screw from
19 the [Grasper] tool fell off while in use in surgery and lodged itself in the body of the plaintiff.”).)
20 Second, the Court previously dismissed Plaintiff’s failure to warn theory because Plaintiff’s
21 allegations were entirely conclusory. (ECF No. 21 at 8.) In the dismissal order, the Court
22 explained Plaintiff needed to “identify which danger was not warned against, explain that the
23 danger was substantial, and that the danger was known or reasonably knowable, or explain how
24 any warning that was given was inadequate.” (*Id.* (citing *Marroquin v. Pfizer, Inc.*, 367 F. Supp.
25 3d 1152, 1160 (E.D. Cal. 2019).) Here, Plaintiff has done just that. Plaintiff alleges the Grasper
26 tool did not have adequate warnings that a screw or pin from the tool could separate itself from
27 the Grasper tool during surgery and significantly harm a patient. (ECF No. 22 ¶¶ 35–36.) At this
28 stage of the proceedings, this is enough. As discussed throughout this order, Plaintiff is not

1 required at this stage to provide documentation or prove her claims as Defendants continuously
2 seem to suggest.

3 As such, the Court DENIES Defendants' Motion to Dismiss Plaintiff's strict liability
4 claim based on a failure to warn theory.

5 B. Negligence

6 "The theories of negligence and strict liability parallel and supplement each other[.]"
7 *Bettencourt v. Hennessy Indus., Inc.*, 205 Cal. App. 4th 1103, 1118 (2012) (internal quotation
8 marks and citation omitted). To recover against a manufacturer under either theory, "a plaintiff
9 must prove that a defect caused injury." *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 479 (2001)
10 (citation omitted). However, under a negligence theory, a plaintiff must also prove "an additional
11 element, namely, that the defect in the product was due to negligence of the defendant." *Id.*
12 (internal quotation and citation omitted).

13 Defendants present the same arguments outlined above for negligence as they do for strict
14 liability. (ECF No. 23 at 12–18.) In opposition, Plaintiff argues she has plausibly stated a claim
15 for negligent products liability. (ECF No. 23 at 22–23.) In reply, Defendants further argue
16 Plaintiff fatally ignores causation by failing to allege how the variance in the Grasper tool led to a
17 screw or pin being left in her body cavity. (ECF No. 34 at 10–11.)

18 The Court previously dismissed Plaintiff's claim because the FAC did not set forth factual
19 allegations describing the manufacturing defect, how the defect differed from its intended design,
20 and about what Defendants failed to warn Plaintiff's surgeons. (ECF No. 21 at 9.) Here, as
21 described above, Plaintiff has remedied those issues. Moreover, the Court finds Plaintiff has
22 sufficiently alleged the defect in the Grasper tool was due to Defendants negligence. (*See* ECF
23 No. 22 ¶ 48.) Plaintiff also clearly alleges causation — Plaintiff alleges due to Defendants'
24 negligence, the Grasper tool failed during surgery, which resulted in a piece of the product being
25 left inside Plaintiff after the surgery, which caused her harm. (*Id.* ¶¶ 54–55.)

26 Accordingly, the Court DENIES Defendants' Motion to Dismiss Plaintiff's negligence
27 claim.

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C. Breach of Express Warranty

A breach of an express warranty occurs when “a seller makes a representation or promise to which its goods do not conform.” *Sukonik v. Wright Med. Tech., Inc.*, No. 14-CV-08278-BRO-MRWX, 2015 WL 10682986, at *11 (C.D. Cal. Jan. 26, 2015) (citing *Brown v. Superior Ct.*, 44 Cal. 3d 1049, 1071 (1988)). To plead breach of an express warranty, Plaintiff must allege facts sufficient to show that “(1) the seller’s statements constitute an affirmation of fact or promise or a description of the goods; (2) the statement was part of the basis of the bargain; and (3) the warranty was breached.” *Weinstat v. Dentsply Int’l, Inc.*, 180 Cal. App. 4th 1213, 1227 (2010) (internal quotations and citation omitted). Additionally, Plaintiff “must adequately plead reliance or privity in order to succeed on a breach of express warranty claim.” *Dei Rossi v. Whirlpool Corp.*, No. 2:12-CV-00125-TLN, 2015 WL 1932484, at *9 (E.D. Cal. Apr. 28, 2015).

Defendants argue Plaintiff’s express warranty claim should be dismissed because the SAC fails to provide any factual allegations regarding the actual express warranty provided. (ECF No. 23 at 18.) According to Defendants, the expanded allegations in the SAC are insufficient to establish the exact terms of the warranty; how the surgeon reasonably relied on the warranty; and how the breach proximately caused Plaintiff’s injury. (*Id.* at 19 (citing ECF No. 22 ¶ 57).)

Plaintiff disagrees and argues the factual allegations in the SAC are sufficient to establish each element required for a breach of express warranty claim. (ECF No. 32 at 26–27 (citing ECF No. 22 ¶¶ 57–59, 61, 62.)) In reply, Defendants contend Plaintiff’s allegations are insufficient to maintain a breach of warranty claim. (ECF No. 34 at 11–12.)

The Court finds Plaintiff has sufficiently cured the defects identified in this Court’s prior order. (*See* ECF No. 21 at 10.) Rather than providing a formulaic recitation of the elements of a breach of express warranty claim, Plaintiff now alleges Defendants expressly represented the Grasper tool would be used in surgery without defect, the tool would remain intact, and the component parts would stay attached to the Grasper tool and not separate or come off while in use. (ECF No. 22 ¶ 58.) Further, Plaintiff alleges these warranties “were one of the factors in the decision” to use the Grasper tool during Plaintiff’s hysterectomy and the surgeon had reasonably relied on these warranties. (*Id.* ¶ 59.) Finally, Plaintiff alleges these warranties were breached

1 when a screw or a pin from the Grasper tool fell off during Plaintiff's surgery and harmed
2 Plaintiff. (*Id.*) Drawing all reasonable inferences in Plaintiff's favor, the Court finds Plaintiff has
3 alleged enough facts to state a claim that is plausible on its face. *Twombly*, 550 U.S. at 570.

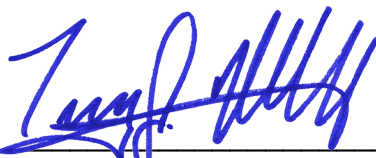
4 Accordingly, Defendants' Motion to Dismiss Plaintiff's breach of express warranty claim
5 is DENIED.

6 **IV. CONCLUSION**

7 For the foregoing reasons, the Court DENIES Defendants' Motion to Dismiss.

8 IT IS SO ORDERED.

9 Date: December 3, 2025

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12 TROY L. NUNLEY
13 CHIEF UNITED STATES DISTRICT JUDGE
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